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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | Complete if Known | | | |
| | | Application Number | 10/534,544 | | |
| | | Filing Date | May, 10, 2005 | | |
| | | First Named Inventor | Shmuel PIETROKOVSKI et al | | |
| | | Group Art Unit | 1645 | | |
| | | Examiner Name | Not Yet Assigned | | |
| Sheet | 1 | Of | 4 | Attorney Docket Number | 29489 |
| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | | |
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | 1 | Amitai et al. "Distribution and Function of New Bacterial Intein-Like Protein Domains", Molecular Microbiology, 47(1): 61-73, 2003. | | | |
| | 2 | Fraser et al. "Novel Neisserial Polypeptides Predicted to Be Useful Antigens for Vaccines and Diagnostics", Database EMBL 'Online!', No. AAY75498, 2000. | | | |
| | 3 | Zhang et al "Construction of A Mini-Intein Fusion System to Allow Both Direct Monitoring of Soluble Protein Expression and Rapid Purification of Target Proteins", Gene, 275(2): 241-252, 2001. P.250, l-h Col., § 3 - P.251, r-h Col., § 1, Figs.1, 3. | | | |
| | 4 | Humphries et al. "Expression of the Class 1 Outer-Membrane Protein of Neisseria Meningitidis in Escherichia Coli and Purification Using A Self-Cleavable Affinity Tag", Protein Expression and Purification, 26(2): 243-248, 2002. P.247, r-h Col., § 2 - P.248, l-h Col., § 2, Fig.1. | | | |
| | 5 | Aspöck et al. "Caenorhabditis Elegans Has Scores of Hedgehog-Related Genes: Sequence and Expression Analysis", Genome Research, 9(10): 909-923, 1999. | | | |
| | 6 | Petrokovski "Intein Spread and Extinction in Evolution", Trends in Genetics 17(8): 465-472, 2001. | | | |
| | 7 | Buell et al. "Filamentous Hemagglutinin, Intein-Containing, Putative", Database Trembl 'Online!', No. Q880E1, 2003. | | | |
| | 8 | Brown et al. "Hypothetical Protein SCP1.201", Database Trembl 'Online!', No. Q9ACV2, 2003. | | | |
| | 9 | Ren "Probable Phenazine Biosynthesis Family Protein", Database Trembl 'Online!', No. Q8EZX6, 2003. | | | |
| | 10 | Gloeckner et al. "Hypothetical Protein RB6107", Database Trembl 'Online!', No. Q7UQT4, 2003. | | | |
| | 11 | Omura et al. "Hypothetical Protein SAV200", Database Trembl. 'Online!', No. Q82RE3, 2003. | | | |
| | 12 | Omura et al. "Hypothetical Protein SAV286", Database Trembl. 'Online!', No. Q82R58, 2003. | | | |
| | 13 | Omura et al. "Hypothetical Protein SAV5292", Database Trembl 'Online!', No. Q82CQ1, 2003. | | | |
| | 14 | Ren "Hypothetical Protein LA3719", Database Trembl 'Online!', No. Q8EZY2, 2003. | | | |
| | 15 | Dassa et al. "Protein Splicing and Auto-Cleavage of Bacterial Intein-Like Domains Lacking A C'-Flanking Nucleophilic Residue", The Journal of Biological Chemistry, 279(31): 32001-32007, 2004. | | | |
| | 16 | Dassa et al. "New Type of Polyubiquitin-Like Genes With Intein-Like Autoprocessing Domains", Trends in Genetics, 20(11): 538-542, 2004. | | | |
| Signature | | Considered | /Oluwatosin Ogunbiyi/ | | 05/04/2008 |

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| 17 | Southworth et al. "Rescue of Protein Splicing Activity From A Magnetospirillum Magnetotacticum Intein-Like Element", Biochemical Society Transactions, 32(Part 2): 250-254, 2004. | | | | |
| 18 | Dassa et al. "Origin and Evolution of Inteins and Other Hint Domains", Nucleic Acids and Molecular Biology, 16: 209-229, 2005. | | | | |
| 19 | Belfort et al. "Homing Endonucleases: Keeping the House in Order", Nucleic Acids Research, 25(17): 3379-3388, 1997. | | | | |
| 20 | Bürglin "Warthog and Groundhog, Novel Families Related to Hedgehog", Current Biology, 6(9): 1047-1950, 1996. | | | | |
| 21 | Cattoli et al. "Separation of MBP Fusion Proteins Through Affinity Membranes", Biotechnological Progresses, 18(1): 94-100, 2002. | | | | |
| 22 | Chong et al. "Protein Splicing Involving the Saccharomyces Cerevisiae VMA Intein", The Journal of Biological Chemistry, 271(36): 22159-22168, 1996. | | | | |
| 23 | Chong et al. "Single-Column Purification of Free Recombinant Proteins Using A Self-Cleavable Affinity Tag Derived From A Protein Splicing Element", Gene, 192: 271-281, 1997. | | | | |
| 24 | Chong et al. "Protein Splicing of the Saccharomyces Cerevisiae VMA Intein Without the Endonuclease Motifs", The Journal of Biological Chemistry, 272(25): 15587-15590, 1997. | | | | |
| 25 | Chong et al. "Modulation of Protein Splicing of the Saccharomyces Cerevisiae Vacuolar Membrane ATPase Intein", The Journal of Biological Chemistry, 273(17): 10567-10577, 1998. | | | | |
| 26 | Chong et al. "Utilizing the C-Terminal Cleavage Activity of A Protein Splicing Element to Purify Recombinant Proteins in A Single Chromatographic Step", Nucleic Acids Research, 26(22): 5109-5115, 1998. | | | | |
| 27 | Clonis "High-Performance Affinity Chromatography (HPAC)", HPLC of Macromolecules: A Practical Approach, IRL Press, Chap.6: 157-182, 1989. | | | | |
| 28 | Coote "Structural and Functional Relationships Among the RTX Toxin Determinants of Gram-Negative Bacteria", FEMS Microbiology Reviews, 88: 137-162, 1992. | | | | |
| 29 | Dalgaard et al. "Statistical Modeling, Phylogenetic Analysis and Structure Prediction of A Protein Splicing Domain Common to Inteins and Hedgehog Proteins", Journal of Computational Biology, 4(2): 193-214, 1997. | | | | |
| 30 | Derbyshire et al. "Genetic Definition of A Protein-Splicing Domain: Functional Mini-Inteins Support Structure Predictions and A Model for Intein Evolution", Proc. Natl. Acad. Sci. USA, 94: 11466-11471, 1997. | | | | |
| 31 | Fouts et al. "Genomewide Identification of Pseudomonas Syringae Pv. Tomato DC3000 Promoters Controlled by the HrpL Alternative Sigma Factor", Proc. Natl. Acad. Sci. USA, 99(4): 2275-2280, 2002. | | | | |
| 32 | Gimble et al. "Homing of A DNA Endonuclease Gene by Meiotic Gene Conversion in Saccharomyces Cerevisiae", Nature, 357(6376): 301-306, 1992. | | | | |
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| | 33 | Guan et al. "Production of Extracellular Domain of Human Tissue Factor Using Maltose-Binding Protein Fusion System", Protein Expression and Purification, 26: 229-234, 2002. | | | |
| | 34 | Tanaka Hall et al. "Crystal Structure of A Hedgehog Autoprocessing Domain: Homology Between Hedgehog and Self-Splicing Proteins", Cell, 91: 85-97, 1997. | | | |
| | 35 | Hammerschmidt et al. "The World According to Hedgehog", Trends in Genetics, 13(1): 14-21, 1997. | | | |
| | 36 | Haselkorn et al. "The Rhodobacter Capsulatus Genome", Photosynthesis Research, 70: 43-52, 2001. | | | |
| | 37 | Hirata et al. "Molecular Structure of A Gene, VMA1, Encoding the Catalytic Subunit of H ⁺ -Translocating Adenosine Triphosphatase From Vacuolar Membranes of Saccharomyces Cerevisiae", The Journal of Biological Chemistry, 265(12): 6726-6733, 1990. | | | |
| | 38 | Jack "Immunoaffinity Chromatography", Molecular Biotechnology, 1: 59-86, 1994. | | | |
| | 39 | James et al. "The Biology of E Colicins: Paradigms and Paradoxes", Microbiology, 142: 1569-1580, 1996. | | | |
| | 40 | Janson et al. "Packings in Affinity Chromatography", Techniques, P.747-781, 1990. | | | |
| | 41 | Jensen et al. "Delayed Extraction Improves Specificity in Database Searches by Matrix-Assisted Laser Desorption/Ionization Peptide Maps", Rapid Communications in Mass Spectrometry, 10: 1371-1378, 1996. | | | |
| | 42 | Kane et al. "Protein Splicing Converts the Yeast TFP1 Gene Product to the 69-KD Subunit of the Vacuolar H ⁺ -Adenosine Triphosphatase", Science, 250(4981): 651-657, 1990. | | | |
| | 43 | Kaufmann et al. "Crystal Structure of the Anti-His Tag Antibody 3D5 Single-Chain Fragment Complexed to Its Antigen", Journal of Molecular Biology, 318: 135-147, 2002. | | | |
| | 44 | Kusmann et al. "Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry Sample Preparation Techniques Designed for Various Peptide and Protein Analytes", Journal of Mass Spectrometry, 32: 593-601, 1997. | | | |
| | 45 | Narayanan "Preparative Affinity Chromatography of Proteins", Journal of Chromatography A, 658: 237-258, 1994. | | | |
| | 46 | Nilsson et al. "Affinity Fusion Strategies for Detection, Purification, and Immobilization of Recombinant Proteins", Protein Expression and Purification, 11: 1-16, 1997. | | | |
| | 47 | Nisnevitch et al. "The Solid Phase in Affinity Chromatography: Strategies for Antibody Attachment", Journal of Biochemical and Biophysical Methods, 49: 467-480, 2001. | | | |
| | 48 | Noren et al. "Dissecting the Chemistry of Protein Splicing and Its Applications", Angewandte Chemie, International Edition, 39: 450-466, 2000. | | | |
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| | 49 | Paulus "Protein Splicing and Related Forms of Protein Autoprocessing", Annual Review of Biochemistry, 69: 447-496, 2000. | | | |
| | 50 | Perler et al. "Protein Splicing and Its Applications", Current Opinion in Biotechnology, 11: 377-383, 2000. | | | |
| | 51 | Perler et al. "Protein Splicing Elements: Inteins and Exteins - A Definition of Terms and Recommended Nomenclature", Nucleic Acids Research, 22(7): 1125-1127, 1994. | | | |
| | 52 | Petrokovski "Conserved Sequence Features of Inteins (Protein Introns) and Their Use in Identifying New Inteins and Related Proteins", Protein Science, 3: 2340-2350, 1994. | | | |
| | 53 | Petrokovski "Modular Organization of Inteins and C-Terminal Autocatalytic Domains", Protein Science, 7: 64-71, 1998. | | | |
| | 54 | Porter et al. "Hedgehog Patterning Activity: Role of A Lipophilic Modification Mediated by the Carboxy-Terminal Autoprocessing Domain", Cell, 86: 21-34, 1996. | | | |
| | 55 | Porter et al. "Cholesterol Modification of Hedgehog Signaling Proteins in Animal Development", Science, 274(5285): 255-259, 1996. | | | |
| | 56 | Sano et al. "Streptavidin-Containing Chimeric Proteins: Design and Production", Methods in Enzymology, 326(19): 305-311, 2000. | | | |
| | 57 | Sano et al. "Genetic Engineering of Streptavidin, A Versatile Affinity Tag", Journal of Chromatography B, 715: 85-91, 1998. | | | |
| | 58 | Schmidt et al. "Molecular Interaction Between the Strap-Tag Affinity Peptide and Its Cognate Target, Streptavidin", Journal of Molecular Biology, 255: 753-766, 1996. | | | |
| | 59 | Schmidt et al. "The Random Peptide Library-Assisted Engineering of A C-Terminal Affinity Peptide, Useful for the Detection and Purification of A Functional Ig Fv Fragment", Protein Engineering, 6(1): 109-122, 1993. | | | |
| | 60 | Sheibani "Prokaryotic Gene Fusion Expression System and Their Use in Structural and Functional Studies of Proteins", Preparations in Biochemistry & Biotechnology, 29(1): 77-90, 1999. | | | |
| | 61 | Shingledecker et al. "Molecular Dissection of the Myobacterium Tuberculosis RecA Intein: Design of A Minimal Intein and of A Trans-Splicing System Involving Two Intein Fragments", Gene, 207: 187-195, 1998. | | | |
| | 62 | Skerra et al. "Applications of A Peptide Ligand for Streptavidin: The Strep-Tag", Biomolecular Engineering, 16: 79-86, 1999. | | | |
| | 63 | Stoddard et al. "Breaking Up Is Hard to Do", Nature Structural Biology, 5(1): 3-5, 1998. | | | |
| | 64 | Vorm et al. "Improved Resolution and Very High Sensitivity in MALDI TOF of Matrix Surfaces Made by Fast Evaporation", Analytical Chemistry, 66(19): 3281-3287, 1994. | | | |
| | 65 | Wilchek et al. "An Overview of Affinity Chromatography", Methods in Molecular Biology, 147: 1-6, 2000. | | | |
| | 66 | Xu et al. "The Mechanism of Protein Splicing and Its Modulation by Mutation", The EMBO Journal, 15(19): 5146-5153, 1996. | | | |
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